SWAT 173: Does a practice-level educational intervention improve the timely assessment of adults with shingles?

Objective of this SWAT
To determine if a “whole practice” educational intervention improves the assessment of patients with shingles within 72 hours of onset of rash, and hence recruitment into the host trial: ATHENA (AmiTriptyline for the prevention of post-HErpetic NeuralgiA).

Study area: Recruitment
Sample type: Patients in a cluster randomised controlled trial
Estimated funding level needed: Medium

Background
Herpes zoster is characterised by a unique painful, blistering, dermatomal rash which is most commonly diagnosed in general practice on symptoms and signs alone. It is often preceded by a prodromal phase, including fever, malaise, dermatomal pain and dysesthesia. Antiviral treatment is recommended as soon as possible after rash onset (but up to 1 week), to treat the rash and reduce acute pain. However, there are currently no preventative treatments for post-herpetic neuralgia (PHN); the most common complication of shingles. The ATHENA trial aims to determine the clinical and cost-effectiveness of prophylactic low-dose amitriptyline for the prevention of PHN.
It is well recognised that participant recruitment into clinical trials is often challenging, slower than expected, and time consuming. Inadequate participant numbers can result in an under powered study, delaying the answer to the question the trial was initially designed to address and/or a type 2 error. (1-3) Indeed, a recent systematic review reported that less than half of studies meet their recruitment targets and recommended the use of Studies Within A Trial (SWATs) to improve the evidence base of effective recruitment strategies. (1) In line with this priority, the purpose of this SWAT is to ascertain if a remotely delivered practice level educational program, aimed at non-clinical staff, improves the timely assessment (within 72 hours of rash onset) of patients with shingles and thereby recruitment to the ATHENA trial. The education program is intended to improve knowledge of shingles (its unique presentation and the benefits of timely treatment) among patient-facing staff working in primary care, especially non-clinical staff. Reception staff in GP surgeries manage access to clinicians and routinely ask about patients’ symptoms, to facilitate an appropriate appointment, with limited training. (4) Therefore, this educational intervention may support them to prioritise patients with shingles-like symptoms for an early appointment.
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Interventions and comparators
Intervention 1: An educational poster, desktop background and one minute animation, which will be distributed to patient-facing staff in primary care at all intervention practices. Each component states what shingles is, common symptoms and signs, and the importance of early assessment to facilitate treatment within one week. Practices will be asked to display the materials for the duration of the SWAT and reminder notices will also be sent.
Intervention 2: No special educational intervention aimed at staff (i.e. continued usual recruitment practice). These control surgeries will receive ATHENA trial posters, designed for patients/display in waiting rooms and practice websites only.

Index Type: Staff education

Method for allocating to intervention or comparator
Cluster (practice level) randomisation 1:1. Randomisation will be stratified by recruiting centre (Bristol, Southampton or Oxford) and minimised on list size and deprivation based on the postcode of the practice.

Outcome measures
Primary: Proportion of patients with clinically diagnosed shingles, who are assessed by a clinician within 72 hours of rash onset.

These data will be collected via an electronic data collection form, completed between randomisation and the end of the internal pilot. When a patient is seen by a clinician with shingles, they will be asked to record the number of days since rash onset on an electronic form.
Secondary: Proportion of patients with clinically diagnosed shingles, who are assessed by a clinician within 144 hours of rash onset (and therefore eligible for recruitment into the ATHENA trial). These data will be collected over the same time period as the primary outcome.

Analysis plans
Analysis will use the intention-to-treat principle. Practice-level characteristics at the time of randomisation will be compared between intervention and control practices using descriptive statistics. The proportion of patients with clinically diagnosed shingles within 72 and 144 hours of rash onset (primary and secondary outcomes, respectively) will be calculated at the practice level. The mean outcomes (weighted for cluster size) will be calculated for each SWAT group along with their confidence intervals. The weighted mean difference between the two groups and confidence interval for that difference will be calculated using weighted linear regression adjusting for variables used in the randomisation.

Possible problems in implementing this SWAT
Intervention practices may not display educational materials (poster and desktop background) or staff may not watch the video even if it is given to them. Knowledge gained by staff from the educational intervention may degrade with time. New staff members may not receive all of the intervention (e.g. animation).

References
1. Treweek S, Pitkethly M, Cook J, Fraser C, Mitchell E, Sullivan F et al. Strategies to improve recruitment to randomised trials. Cochrane Database of Systematic Reviews 2018;(2):MR000013.
2. Watson JM, Torgerson DJ. Increasing recruitment to randomised trials: a review of randomised controlled trials. BMC Medical Research Methodology 2006:34.
3. Sood A, Prasas K, Chhatwani L, Shinozaki E, Cha S, Loehrer L, et al. Patient's attitudes and preferences about participation and recruitment strategies in clinical trials. Mayo Clinic Proceedings 2009;3:243-7.
4. Slaying the dragon myth: an ethnographic study of receptionists in UK general practice. BJGP 2013;(March):e177-84.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Matthew Ridd.
Contact email address: athena-study@bristol.ac.uk
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